



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/606,763 06/29/00 CHEN

H 1440.1043-00

EXAMINER

HM22/0914

DOREEN M HOGLE ESQ  
HAMILTON BROOK SMITH & REYNOLDS PC  
TWO MILITIA DRIVE  
LEXINGTON MA 02421-4799

ART UNIT

PAPER NUMBER

1653  
DATE MAILED:

09/14/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.

09/606,763

Applicant(s)

CHEN ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-89 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claim 69 is an improper dependent claim, it has been treated to be dependent from claim 68 for restriction purpose.

#### *Election/Restrictions*

- I. Restriction to one of the following inventions is required under 35 U. S. C. 121:
  - I. Claims 1-7, 12-13, 17, 19 and 37-42, drawn to a purified hCOMP, an ELISA kit or a composition comprising the hCOMP, classified in class 514, subclass 2.
  - II. Claims 8-11, drawn to a method for producing purified hCOMP, classified in class 435, subclass 69.1.
  - III. Claims 14-16, 18 and 20, drawn to an antibody to the hCOMP or an ELISA kit comprising the antibody to the hCOMP, classified in class 424, subclass 130.1.
  - IV. Claims 21-36, drawn to an implant comprising a matrix comprising the hCOMP, classified in class 514, subclass 2.
  - V. Claims 43-57, drawn to a method of repairing cartilage comprising implanting into the defect area a matrix comprising hCOMP, classified in class 514, subclass 2.
  - VI. Claims 58-61, drawn to a method for making an implant for cartilage repair comprising binding a differentiation agent to hCOMP, adding the differentiation agent-bound hCOMP to a matrix and adding chondrogenic cells to the matrix, classified in class 514, subclass 2.
  - VII. Claims 62-67 and 70, drawn to a method for transplanting chondrocytes or mediating attachment of chondrocytes in autologous transplantation, classified in class 435, subclass 325.

Art Unit: 1653

VIII. Claim 68, drawn to a method for producing chondrocytes for autologous transplantation, classified in class 435, subclass 325.

IX. Claim 69, drawn to chondrocytes, classified in class 435, subclass 325.

X. Claims 71 and 72, drawn to a method of preparing a cartilage repair implant comprising culturing cells expressing COMP, purifying COMP and adding it to a matrix, classified in class 514, subclass 2.

XI. Claims 73-75, drawn to a method for making an implant for cartilage repair comprising culturing chondrogenic cells in vitro in the presence of hCOMP bound to a differentiation agent, and seeding the chondrogenic cells into a matrix, classified in class 514, subclass 2.

XII. Claims 76-79, 81, 84-87, drawn an assay for determining the amount of COMP in a biological sample using the antibody to hCOMP, classified in class 424, subclass 130.1.

XIII. Claim 80, drawn an assay to detect anti-COMP antibodies in a biological sample using the hCOMP, classified in class 424, subclass 130.1.

XIV. Claims 82-83 and 88-89, drawn to a method of diagnosing arthritis or inflammatory joint disease in a mammal comprising detecting and measuring COMP, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

The method of Invention II and the product of Invention I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

Art Unit: 1653

(MPEP § 806.05(f)). In the instant case the product as claimed can be made by chemical synthesis.

The products of Inventions I, III and IV are patentably distinct from each other because these products are physically and functionally distinct chemical entities, they have different sequences and different modes of operation. For example, the products of Invention I are proteins which can be used to make the products of Invention III, antibodies, while products of Invention IV are implants which contain a matrix including the protein and other polymers.

The product of Invention I and the methods of Inventions VI, X, XI and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Invention I can be used in an alternate method of Inventions VI, X, XI and XIII.

The product of Invention III and the methods of Inventions XII and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Invention I can be used in an alternate method of Inventions XII and XIV.

The product of Invention IV and the method of Invention V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

Art Unit: 1653

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of Invention V can use the product of chondrogenic cells with purified hCOMP.

The product of Invention I is distinct from methods of Inventions V, VII-IX, XII and XIV because the products of Invention I can neither be made nor used by methods of Inventions V, VII-IX, XII and XIV.

The product of Invention III is distinct from methods of Inventions II, V-XI and XIII because the products of Invention III can neither be made nor used by methods of Inventions II, V-XI and XIII.

The product of Invention IV is distinct from methods of Inventions II and VI-XIV because the products of Inventions IV can neither be made nor used by methods of Inventions II and VI-XIV.

The methods of Inventions II and V-XIV are patentably distinct from each other because the method steps and outcomes are wholly different between these inventions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classification and the recognized divergent subject matter, and because Inventions I-XIV require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Art Unit: 1653

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.  
Patent Examiner

\*\*\*

September 10, 2001

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600